

G.W. only

Scope Paper
Health Committee Report Session

1. Objectives of the Meeting

The following objectives reflect the fact that this is the first meeting of the Health Committee:

- a. Reach agreement on several documents, as follows, which will establish the foundation for the Committee actions/operations:
 - Committee membership
 - Charge to the Health Committee
 - Methods of work
 - Role of Secretariats to the Committee
- b. Review programs and activities being carried out under the new U.S.-Russia Health Agreement, signed in January 1994; similarly review other cooperation in the health sector, with emphasis on USAID technical support to Russia, which is related to G-C Health Committee interests.
- c. Announce initiatives where at least one will impact people "on the ground."
 - Women's Reproductive Health Initiative
This new USAID-supported program will address high levels of maternal mortality and morbidity caused by a high incidence of abortion. The initiative will include education for women and health professionals on contraceptive methods and the establishment of model family planning centers in approximately six oblasts.
 - Cooperation in the Pharmaceutical Sector
This USAID-funded program will accelerate investment by U.S. pharmaceutical firms in Russia for the production of critically needed drugs. Partnerships will be developed between U.S. pharmaceutical firms and the Russian pharmaceutical industry.

Announce the donation of surplus DOD hospital equipment and supplies to a hospital in Vladivostok.

The United States will donate an estimated \$6 million in hospital equipment and supplies from a DOD hospital in Japan that is being decommissioned to Vladivostok Hospital Number 2. This hospital was selected to receive this shipment because of the Vladivostok's geographic location (closer to Japan) and because there is a USAID-supported partnership between Hospital Number 2 and the Medical College of Virginia at Virginia Commonwealth University, Richmond. The U.S. partnership hospital will assist in assuring that equipment is properly placed and in training hospital personnel. Moreover, Vladivostok Hospital Number 2 is a center for general surgery and emergency/critical care. A significant portion of the supplies and equipment from the DOD hospital are surgery and trauma related. The equipment is expected to be delivered in mid-1995.

- d. **Agree on priorities for cooperation.** The following areas have been agreed upon at a senior staff level, with four put forward by the Russians and four areas by the U.S.:

- Diabetes
- Health Education and Promotion
- Prevention and Control of Infectious Diseases
- Strengthening Primary Care Practice
- Tuberculosis Treatment and Control
- Maternal and Child Health
- Health Reform and Policy Dialogue
- Environmental Health

Note on AIDS. While HIV/AIDS has not been explicitly identified as a priority, it can be encompassed within the priority areas "Health Education and Promotion" and "Prevention and Control of Infectious Diseases." There is also a relationship between the "Tuberculosis Treatment and Control" area and HIV/AIDS. The U.S. delegation will raise HIV/AIDS as an area of interest, among others, within the agreed priority areas. It should be noted that there has been discussion and exchange of information between the U.S. and Russia on HIV/AIDS. Russian health officials have not, however, identified HIV/AIDS as a high priority at this time, in

light of its relatively low incidence. They have a deeper concern about environmental health issues (which are extensive); improving control of infectious diseases, including immunization coverage (e.g. they have an ongoing diphtheria epidemic); and reducing the cost to their health system of such diseases as diabetes. Life expectancy for males in the Russian Federation is now only 59 years, reflecting a high level of morbidity and mortality from cardiovascular disease, cancer, accidents, and violence.

- e. Identify appropriate next steps to be implemented through the Secretariats. In most cases, this will involve getting experts from Russia and the U.S. together. Out of this will flow action plans. In the diabetes prior area, for example, a visit to the U.S. by a Russian team in an area of high priority to them.
- f. Address the lack of progress toward implementation of the Drugs and Biological Products Memorandum of Understanding between Russian health authorities and the Food and Drug Administration.

2. Overview and status

a. Key Issues

1. Bringing about a constructive role for the Ministry of Health and Medical Industry

An ongoing issue in U.S.-Russia cooperation in the health sector is the role of the Ministry of Health and Medical Industry. It is hoped that the Health Committee may be able to help the Ministry to develop a more effective way of doing business and that the Health Committee will become a positive force for identification and removal of obstacles both to cooperation between the U.S. and Russia as well as in bring about improvements in health status in Russia.

2. Announcement of two new USAID initiatives and related issues

- a. While it has been agreed that two new USAID initiatives -- Women's Reproductive Health and Cooperation in the Pharmaceutical Sector -- will be announced, this has not been without difficulty. The Ministry of Health,

while agreeing in principle to announcement of the Pharmaceutical Sector Project (this would involve USAID awards to four U.S. firms to develop partnerships with Russian organizations for pharmaceutical production and related efforts), the Ministry has not yet given its concurrence with the four proposed awards. Their concurrence is essential inasmuch as the Ministry of Health and Medical Industry has the authority in the Russian Government to license products for sale in the country. Moreover, they are key to assuring a reasonable market for the products in the country.

- b. Additionally, U.S. firms (Merck, in particular) are requesting certain tax concessions as well as market guarantees. These issues may be dealt with, in part, through the Business Development Committee. While these issues could be touched on during this meeting, they will require further discussion to reach resolution.

3. FDA-Russia MOU

- a. There remain persistent reports that there are significant drug shortages of important drugs in Russia, causing morbidity and mortality.
- b. Approximately 600 essential drugs are not manufactured in Russia, including hormone based products, insulin, cardiovascular drugs, gastro-intestinal drugs, cephalosporin antibiotics, and drugs used in transplantation. Shortages in nearly every class of pharmaceutical products, along with other factors, have resulted in a marked increase in vaccine preventable and other treatable diseases.
- c. To expedite the registration in Russia of FDA-approved and U.S.-produced pharmaceuticals, an FDA-Russia MOU on Drugs and Biological Products was signed in February 1994. It was signed by Russian Minister of Health Nechayev and the head of the State Committee for Sanitary and

Epidemiological Surveillance, Dr. E. Beliaev, as well as by numerous other Russian health officials. To date, the MOU has not been fully implemented. U.S. pharmaceutical companies seeking expedited registration under the MOU face continual problems in getting Ministry of Health to market their products in Russia. Secretary Shalala will raise this with Minister Nechayev at her one-on-one dinner on December 13.

b. Successes and problem areas.

1. Key documents (e.g. charge to committee, methods of work) have been drafted and shared with the Russians.
2. The leveraging of resources on both sides will be a continuing issue in the Committee's work. In this connection, the U.S. side needs to push themes directed toward mobilization of know-how and coordination of efforts such that the whole is indeed is greater than the sum of the individual parts.
3. Also see above

c. Committee priorities for the future.

1. Identifying obstacles to cooperation in the health sector and development of approaches to assure removal of those obstacles.
2. Assuring that appropriate plans are developed, through mechanisms established by the Secretariats, for the priority areas agreed upon by the Committee.
3. Assuring maximum planning and coordination among potential partners and participants in areas identified by the Committee, including industry and other private organizations.
4. Assuring the implementation of the Drugs and Biological Products Memorandum of Understanding Between Russian Health Authorities and the Food and Drug Administration